

July 29, 1999

Clinton/Gore FDA Violated 1st Amendment

Court Restores Doctors' Free Speech Rights

In a opinion released yesterday, U.S. District Court Judge Royce C. Lamberth declared unconstitutional parts of a 1997 Food and Drug Administration (FDA) reform law. The ruling is a victory for the First Amendment, a victory for patients who rely on timely information about medical advances, and a vindication of Republicans who fought for the now-invalidated law as a way to loosen the FDA's suppression of medical speech.

At issue is the right of doctors to receive truthful information from drug and medical device manufacturers regarding new uses for products already approved by the FDA. While the FDA approves products for a specific use, researchers often find new uses for a product after it is approved. But only FDA-approved uses may appear on the product's label. Therefore, the new uses are called "off-label" uses.

Often, these "off-label" uses are life-saving innovations or become the standard of care. For example, researchers recently found a 40-year old generic drug meant to treat water retention also prevents heart failure deaths and could save tens of thousands of lives per year. Doctors are free to prescribe medicines for "off-label" uses. In some instances, a doctor could be charged with malpractice if he did *not* make an "off-label" prescription.

However, the Clinton/Gore FDA has prohibited manufacturers from sending doctors information about "off-label" uses. The agency claims that if the FDA has not approved the new use, sending doctors even truthful information about it (including articles from medical journals and textbooks) would be "inherently misleading." Perversely, the FDA's policy denies doctors and patients information on innovative and life-saving therapies.

In 1994, a group of doctors (represented by the Washington Legal Foundation, a free-market consumer group) sued the FDA for violating their First Amendment rights. (Interestingly, the drug and medical device industries declined to challenge the regulations.)

On July 30, 1998, Judge Lamberth struck down the FDA's regulations because, as the court explained yesterday, "the FDA was violating the First Amendment rights of plaintiff's members by unduly limiting the manner in which drug manufacturers may disseminate information relating to unapproved — or 'off-label' — uses of FDA-approved drugs."

In the meantime, however, Republicans had clipped the FDA's wings. Senators Bill Frist (R-TN) and Connie Mack (R-FL) amended the FDA Modernization Act of 1997 (FDAMA) to curtail the FDA's censorship, despite fierce opposition from Senator Ted Kennedy (D-MA).

Cagily, the FDA asked the court to set aside its ruling, claiming the FDAMA superseded the agency's previous policies. Instead, the court ruled:

[T]he FDAMA largely perpetuates the policies held unconstitutional by the Court on July 30, 1998 and therefore may not be applied or enforced by FDA.

In particular, the FDA argued that because the FDAMA diminishes the agency's ability to restrict — and in fact “affirmatively permits” — “off-label” speech, whatever censorship persists should not be subject to First Amendment scrutiny. The Court replied:

This is, of course, preposterous. The First Amendment is premised upon the idea that people do not need the government's permission to engage in truthful, non-misleading speech about lawful activity. . . . [T]he government could not justify a law criminalizing criticism of the government on the theory that such a law would “affirmatively permit” pro-government speech. Neither can the FDA escape judicial review of its speech restrictions on the theory that they “permit” speech that complies with the FDA's wishes.

The court continued:

The government, however benign its motivations, simply cannot justify a restriction of truthful non-misleading speech on the paternalistic assumption that such restriction is necessary to protect the listener from ignorantly or inadvertently misusing the information. . . . [T]his axiom is particularly powerful where the recipient of information is a sophisticated listener trained extensively in the use of such information — as are the doctors and other health care providers in this case.

Amazingly, the Clinton/Gore Administration may appeal the ruling.

Judge Lamberth's ruling reaffirms the importance of free speech — commercial or otherwise. In this case, suppressing speech left doctors and patients in the dark about new treatments. The ruling affirms doctors' First Amendment rights, for censorship harms both those who wish to transmit information and those who wish to receive it. Most importantly, it is a victory for patients, who bore the pain caused by censorship of “off-label” treatments.

Finally, the ruling vindicates Republicans who took on the Clinton/Gore Administration and congressional Democrats in an attempt to help patients get the best medical care available.

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